

REMARKS

This Amendment is responsive to the Office Action mailed June 25, 2007. After entry of this Amendment, claims 1, 2, and 4-13 are currently pending in this application and subject to examination. Claim 3 is cancelled without prejudice or disclaimer. Claims 1 and 10-13 are amended. Support for these amendments is found in claim 3 as originally filed and at page 5, line 35 to page 6, line 2 of the present specification. No new matter has been added.

Reconsideration of the application as amended is respectfully requested in view of the following remarks.

Priority

Pursuant to 35 U.S.C. § 119(b)(3) and 37 C.F.R. §§ 1.55(a)(4)(i)(B) and (C), a copy of the certified English translation of Applicants' foreign priority document DE 102 37 442.2, filed August 16, 2002, is filed concurrently herewith. Applicants will submit the original certified English translation of Applicants' foreign priority document if the Examiner so requires. Pursuant to 37 C.F.R. § 1.55(a)(4)(ii), two Certifications of Translation, wherein translator Elise Duvekot states that her translations of DE 102 37 442.2 and its Priority Certificate are accurate, are also filed concurrently herewith. This establishes that the earliest effective filing date of the present application is August 16, 2002.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 10 and 11 stand rejected as indefinite under 35 U.S.C. § 112, second paragraph, for reciting the phrase "conventional additions." Specifically, the Examiner asserts that both the claims and specification are unclear as to what constitute conventional additions for a dialysis solution or a plasma expander and, as a result, this phrase is not in any way limiting. Applicants respectfully traverse. However, in the interest of expediting prosecution, Applicants have amended claims 10 and 11 to delete this phrase.

Withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 3, 5, 11, and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Application Pub. No. 2004/0157207 to Sommermeyer et al. (hereinafter “Sommermeyer I”), which published in English on August 12, 2004. Sommermeyer is the publication of U.S. Application Serial No. 10/486,943, which is the national stage under 35 U.S.C. § 371 of International Application PCT/EP02/08757, which was filed August 6, 2002 and which published in German on March 6, 2003 as WO/018639 A1. In turn, PCT/EP02/08757 claims the benefit of DE 101 41 099.9, which was filed August 22, 2001. The Examiner asserts that DE 101 41 099.9 was published on July 23, 2002. Applicants respectfully traverse.

Applicants established *supra* by submission of a certified English translation of Applicants’ foreign priority document DE 102 37 442.2 that the earliest effective filing date of the present application is August 16, 2002. This date is earlier in time than the March 6, 2003 publication date of WO/018639 A1. As such, WO/018639 A1 cannot be relied upon to reject claims 1, 3, 5, 11, and 13 as anticipated under 35 U.S.C. § 102(b).

In addition, DE 101 41 099.9 cannot be relied upon to reject claims 1, 3, 5, 11, and 13 as anticipated under 35 U.S.C. § 102(b) because it did not publish on July 23, 2002, as asserted by the Examiner. The July 23, 2002 date that appears on the Priority Certificate is not the date the application published, but rather the date the Priority Certificate was signed by the proxy of the German Patent and Trademark Office President. *See, e.g.*, the certified English translation of the Priority Certificate of Applicant’s foreign priority document, which also has such a signature, dated July 21, 2003. Applicants have informed the undersigned that, after checking the database of the German Patent and Trademark Office, DE 101 41 099.9 did not publish. Applicants have also informed the undersigned that a “follow-up” application was instead filed (DE 102 35 954.7, filed August 6, 2002) claiming the “inner priority” of DE 101 41 099.9. Applicants have further informed the undersigned that this claim to “inner priority” has the legal effect of deeming DE 101 41 099.9 withdrawn. A copy of DE 102 35 954.7 is attached as Exhibit A. Please note that this application did not publish until March 6, 2003. This date is later in time than Applicant’s

earliest effective filing date of August 16, 2002. As such, DE 102 35 954.7 also cannot be relied upon to reject claims 1, 3, 5, 11, and 13 as anticipated under 35 U.S.C. § 102(b).

Withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-3, 5-8, 11, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,218,108 to Sommermeyer et al. (hereinafter "Sommermeyer II") in view of U.S. Patent Application Publication No. 2002/0065410 to Antrim (hereinafter "Antrim"). Claims 1-4, 6-8, 10, and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,284,140 to Sommermeyer et al. (hereinafter "Sommermeyer III") in view of Antrim. Claims 1-3, 5-8, 11, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over Sommermeyer II in view of Sommermeyer I. Claims 1-4, 6-8, 10, and 12 stand rejected under 35 U.S.C. § 103(a) as obvious over Sommermeyer III in view of Sommermeyer I. Claim 9 stands rejected under 35 U.S.C. § 103(a) as obvious over any one of (1) Sommermeyer I, (2) Sommermeyer II in view of Antrim, (3) Sommermeyer III in view of Antrim, (4) Sommermeyer II in view of Sommermeyer I, and (5) Sommermeyer III in view of Sommermeyer I, and in further view of WO 00/33851 A1 to Naggi et al. (hereinafter "Naggi"). Applicants respectfully traverse.

Rejection of Claims 1-3, 5-8, 11, and 13 Over Sommermeyer II in View of Antrim

The Examiner rejected claims 1-3, 5-8, 11, and 13 as obvious over Sommermeyer II in view of Antrim on the grounds that (1) Sommermeyer II teaches a hydroxyethyl starch having all of the limitations of these claims except for the recited degree of branching in the range of from 8-20 mol %, (2) Antrim teaches this missing limitation, (3) that persons of ordinary skill in the art would have been motivated to combine the teachings of Sommermeyer II and Antrim in the manner proposed by the Examiner because "Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications." See page 4, line 18 to page 5, line 13 of the June 25, 2007 Office Action.

Claims 1-3, 5-8, 11, and 13 are non-obvious because there is no motivation to combine the teachings of Sommermeyer II and Antrim. As pointed out *supra*, the only motivation asserted by the Examiner is that “Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications.” See page 5, lines 11-13 of the June 25, 2007 Office Action. However, Sommermeyer II only seeks to improve the ability its hydroxyethyl starches to (1) completely breakdown within a physiologically reasonable time and (2) exhibit controllable elimination behavior, not their solution stability. See column 2, lines 58-65 of Sommermeyer II. In fact, Sommermeyer II teaches that its hydroxyethyl starches already exhibit “an *adequately high solubility* in aqueous medium so that the solutions are stable even for relatively long periods of time.” See column 3, lines 55-62 of Sommermeyer II. As such, Sommermeyer II *teaches away* from improving the solution stability of its hydroxyethyl starches using the teaching of Antrim. A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. See MPEP § 2141.03 (VI) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)) It is improper to combine references where the references teach away from their combination. See MPEP § 2145 (X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Since it is improper to combine the teachings of Sommermeyer II and Antrim, the Examiner has failed to establish that claims 1-3, 5-8, 11, and 13 are obvious.

Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-4, 6-8, 10, and 12 Over Sommermeyer III in View of Antrim

The Examiner rejected claims 1-4, 6-8, 10, and 12 as obvious over Sommermeyer III in view of Antrim on the grounds that (1) Sommermeyer III teaches a hydroxyethyl starch having all of the limitations of these claims except for the recited degree of branching in the range of from 8-20 mol %, (2) Antrim teaches this missing limitation, and (3) that persons of ordinary skill in the art would have been motivated to combine the teachings of Sommermeyer III and Antrim in the manner proposed by the Examiner because “Antrim discloses that highly branched

starches are more stable in solution, and thus more useful for a wide variety of applications.” *See* page 6, lines 4-22 of the June 25, 2007 Office Action.

Claims 1-4, 6-8, 10, and 12 are non-obvious because there is no motivation to combine the teachings of Sommermeyer III and Antrim. As pointed out *supra*, the only motivation asserted by the Examiner is that “Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications.” *See* page 6, lines 19-22 of the June 25, 2007 Office Action. However, nowhere in Sommermeyer III is there any suggestion that improvement of the stability of its hydroxyethyl starch-based peritoneal dialysis solutions is desirable. Furthermore, Sommermeyer III incorporates by reference the entire disclosure of Sommermeyer II as an example of a process for preparing the hydroxyethyl starches useful in preparing its peritoneal dialysis solutions. *See* column 3, lines 7-16 of Sommermeyer III. As such, persons of ordinary skill in the art would lack motivation to look to the teachings of Antrim or any other reference, since Sommermeyer III already teaches how to prepare hydroxyethyl starches that have “an adequately high solubility in aqueous medium so that the solutions are stable even for relatively long periods of time.” *See supra*. Thus, like Sommermeyer II, Sommermeyer III *teaches away* from being combined with Antrim. Since it is improper to combine the teachings of Sommermeyer III and Antrim, the Examiner has failed to establish that claims 1-4, 6-8, 10, and 12 are obvious.

Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-3, 5-8, 11, and 13 Over Sommermeyer II in View of Sommermeyer I

The Examiner rejected claims 1-3, 5-8, 11, and 13 as obvious over Sommermeyer II in view of Sommermeyer I on the grounds that (1) Sommermeyer II teaches a hydroxyethyl starch having all of the limitations of claim 1 except for the recited degree of branching in the range of from 8 to 20 mol % and (2) Sommermeyer I teaches this missing limitation. *See* page 7, line 14 to page 8, line 12 of the June 25, 2007 Office Action.

As discussed *supra*, the Examiner cannot rely on Sommermeyer I as a prior art reference since (1) the earliest publication date of the subject matter of this reference is March 6, 2003

(i.e., the publication date of DE 102 35 954.7 and WO/018639 A1) and (2) Applicants have established that the earliest effective filing date of the present application is August 16, 2002, which is prior to March 6, 2003. Establishment of *prima facie* obviousness of a claimed invention requires that all of the claim limitations be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1975). The Examiner asserts that Sommermeyer I teaches the degree of branching limitation recited in claims 1-3, 5-8, 11, and 13. However, since Sommermeyer I cannot be relied upon as a prior art reference, the Examiner has failed to show that all of the limitations of claims 1-3, 5-8, 11, and 13 are taught or suggested by the prior art. As such, the Examiner has not established that these claims are *prima facie* obvious.

Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-4, 6-8, 10, and 12 Over Sommermeyer III in View of Sommermeyer I

The Examiner rejected claims 1-4, 6-8, 10, and 12 as obvious over Sommermeyer III in view of Sommermeyer I on grounds that (1) Sommermeyer III teaches a hydroxyethyl starch having all of the limitations of these claims except for the recited degree of branching in the range of from 8-20 mol % and (2) Sommermeyer I teaches this missing limitation. *See* page 9, line 5 to page 10, line 7 of the June 25, 2007 Office Action.

Applicants incorporate herein by reference in their entirety the remarks made *supra* regarding the obviousness rejection of claims 1-3, 5-8, 11, and 13 over the combination of Sommermeyer II in view of Sommermeyer I. For the same reasons, the Examiner cannot rely on Sommermeyer I as a prior art reference in combination with Sommermeyer III to reject these claims. Since Sommermeyer I cannot be relied upon as a prior art reference, the Examiner has failed to show that all of the limitations of claims 1-4, 6-8, 10, and 12 are taught or suggested by the prior art. As such, the Examiner has not established that these claims are *prima facie* obvious.

Withdrawal of this rejection is respectfully requested.

Rejection of Claim 9

The Examiner rejected claim 9 as obvious over any one of (a) Sommermeyer I, (b) Sommermeyer II in view of Antrim, (c) Sommermeyer III in view of Antrim, (d) Sommermeyer II in view of Sommermeyer I, and (e) Sommermeyer III in view of Sommermeyer I, as applied to claims 1-4, 6-8, and 10-13, and in further view of Naggi on grounds that (1) (a), (b), (c), (d), and (e) all teach a hydroxyethyl starch having all of the limitations of claim 9 except for a starch in which the reducing end has been inactivated by oxidation or reduction; (2) Naggi teaches this missing limitation; and (3) that persons of ordinary skill in the art would have been motivated to combine the teachings of (a), (b), (c), (d), and (e) with Naggi in the manner proposed by the Examiner because Naggi discloses that inactivating the reducing end via oxidation or reduction "allows the starch to be autoclaved without forming toxic degradation products such as formaldehyde." *See* page 11, lines 7-20 of the June 25, 2007 Office Action.

Applicants incorporate herein by reference in their entirety the remarks made *supra* regarding the anticipation rejection of claims 1, 3, 5, 11, and 13 over Sommermeyer I and the obviousness rejections of claims 1-8 and 10-13 over the combinations of Sommermeyer II in view of Antrim, Sommermeyer III in view of Antrim, Sommermeyer II in view of Sommermeyer I, and Sommermeyer III in view of Sommermeyer I. Naggi does not disclose the degree of branching in the range of from 8-20 mol % recited by claim 9. Naggi also does not mitigate the impropriety of combining the teachings of Sommermeyer II or III with Antrim. Therefore, because (1) Sommermeyer I cannot be relied upon by the Examiner as a prior art reference, (2) Naggi does not disclose the degree of branching recited in claim 9, and (3) it is improper to combine the teaching of Antrim with those of Sommermeyer II or III, which teach away from this combination, the Examiner has failed to establish that claim 9 is obvious.

Withdrawal of this rejection is respectfully requested.

Provisional Obviousness-Type Double Patenting Rejection

Claims 1, 3, 5, and 10 stand provisionally rejected as unpatentable over claims 1, 2, 6, and 7 of co-pending U.S. Application Serial No. 10/486,943 (published as Sommermeyer I). Specifically, the Examiner asserts that claims 1, 3, 5, and 10 of the present application are not patentably distinct from claims 1, 2, 6, and 7 of Sommermeyer I on the basis that (1) claims 1, 6, and 7 of Sommermeyer I claim a hyperbranched amylopectin having the same molecular weight and degree of branching as the modified starch product of claims 1, 3, 5, and 10 and (2) claim 2 of Sommermeyer is directed to the use of said hyperbranched amylopectin as a plasma volume expander. Applicants respectfully traverse. Applicants note that there are no assignees or inventors in common between the present application and Sommermeyer I. *See* (1) the assignment of the present application recorded with the USPTO at reel/frame 015954/0742 and (2) the assignment of Sommermeyer I recorded with the USPTO at reel/frame 015140/0800. As such, an obviousness-type double patenting rejection of claims 1, 3, 5, and 10 over claims 1, 2, 6, and 7 of Sommermeyer I is improper. However, in the interest of expediting prosecution, Applicants have amended claims 1 and 10-13 to exclude derivation of the unsubstituted or hydroxyethyl- or hydroxypropyl-substituted starch product of these claims from an amylopectin fraction. Support for this amendment is found in the present specification at page 5, line 35 to page 6, line 2. Claims 1 and 10, as amended, are now patentably distinct from claims 1, 2, 6, and 7 of Sommermeyer I. Claim 5 is also now patentably distinct from claims 1, 2, 6, and 7 of Sommermeyer I by virtue of its dependency from amended claim 1. This rejection is moot as to claim 3, which is cancelled.

Withdrawal of this rejection is respectfully requested

In view of the above amendment and remarks, Applicants believe the pending application is in condition for allowance.

The Director is authorized to charge \$460.00 to Deposit Account No. 03-2775, under Order No. 09600-00028-US, to cover the extension fee required by 37 C.F.R. § 1.17(a)(2). Should any other fees be required in connection with this Amendment, the Director is hereby authorized to charge any fees due or outstanding, including any extension fees, or credit any overpayment, to Deposit Account No. 03-2775, under Order No. 09600-00028-US from which the undersigned is authorized to draw.

Dated: November 13, 2007

Respectfully submitted,

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